STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED COMMISSION

ORAL TESTIMONY
PUBLIC HEARING REVIEW STANDARDS FOR URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (UESWL) SERVICES

Thursday, July 24, 2003
Michigan Library and Historical Center
702 West Kalamazoo
Lansing, Michigan

Approximately 33 people were in attendance.

(Proceedings scheduled to start at 10:00 a.m.; actual start time was 10:01 a.m.)

MS. ROGERS: Good morning. My name is Brenda Rogers. I am special assistant to the Certificate of Need Commission from the Department of Community Health. Chairperson Renee Turner-Bailey has asked the Department to conduct today's hearing. We are here today to take testimony concerning potential language revisions to the Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy or UESWL Services/Units. Please be sure that you have signed the sign-in log. Copies of the current CON Review Standards can be found on the table as well as cards to be completed if you wish to provide testimony. Please hand your card to me if you wish to speak.

Additionally, if you have written testimony and/or other documentation/data pertaining to any potential modifications to the CON Review Standards, please provide a copy as well. Further, please state and print your name and organization on the sign-in sheet located at the podium. As indicated on the card, written testimony and/or other documentation/data may be provided to the Department through July 31st, 2003, at 5:00 p.m.

We will begin the hearing by taking testimony from those of you who wish to speak. The hearing will continue until all testimony has been given, at which time we will adjourn. Today is Thursday, July 24th, 2003, and we are now taking testimony. Do I have anybody that wishes to provide testimony regarding the lithotripsy? Cheryl Miller with Trinity Health.

MS. MILLER: Good morning. My name is Cheryl Miller. I'm senior manager in Corporate Strategic Planning at Trinity Health. Thank you for the opportunity to provide input on the possible changes to the current CON Review Standards for lithotripsy.

Several Trinity Health hospitals around the state currently have CON approval to be mobile host sites for lithotripsy. These hospitals are experiencing volumes significantly in excess of original projections. As a result, current wait times are as long as eight weeks due to the lack of available time slots. This excessive wait is resulting in unacceptable patient pain and discomfort and frequent necessity to subject patients to the insertion of urinary stents until a

lithotripsy time slot becomes available. In addition, these stenting procedures unnecessarily increase the cost of care for patients with kidney stone disease.

The Trinity Hospitals with current mobile lithotripsy service support changes to the CON Review Standards to allow for the expansion of existing mobile services. Other aspects of these standards may need review, but we feel that expansion of existing mobile service warrants immediate attention. Thank you.

MS. ROGERS: Thank you. Robert Meeker representing Spectrum Health. And are you speaking on behalf of Alliance for Health as well?

MR. MEEKER: (Nodding head in affirmative)

MS. ROGERS: Okay. Thank you.

MR. MEEKER: I'm Bob Meeker from Spectrum Health in Grand Rapids, and I'll speak on behalf of Alliance for Health in just a moment. Spectrum Health in Grand Rapids has provided through the West -- the Spectrum Health Stone Center, fixed lithotripsy services for West Michigan for the last more than 15 years now, 16 years. We have a unique open-staff model whereby urologists from the entire western side of the state have privileges at the Stone Center, even though perhaps they wouldn't be privileged for other services at the hospital. We currently operate an HM3, the first generation lithotriptor, which, I think, is generally acknowledged as being the "gold standard." And, in fact, many of the urologists come to our facility to use that machine. Even though perhaps mobile lithotripsy might be available closer to their home, they believe in the HM3.

We have been operating pretty steadily in excess of the standards, but not a whole lot in excess of the standards. For the last four years we have been right around 1100 procedures a year. It has not grown; it has not shrunk. The market for lithotripsy in West Michigan is pretty stable. We don't need additional capacity. The existing service serves West Michigan very well; however, there is a problem. The problem is twofold: One, recently mobile lithotripsy has been approved to enter into West Michigan. You know, according to the standards, it was, you know, a legitimate approval. But that machine will begin to erode the volume that we have had. The end result likely will be a reduction in lithotripsy service in West Michigan in the future. The HM3, as solid and as wonderful as it is, hasn't been manufactured for years, and replacement parts are getting more and more difficult to obtain, so that it is going to need to be replaced, and it can't be replaced with the same machine unfortunately. The problem is that, if our volumes erode to a point where we are no longer meeting standards, no longer performing 1,000 procedures a year, we will not be able to replace it with the fixed model that has been so successful in West Michigan in the past, so that the irony would be that, by bringing in more service, the mobile lithotriptor, which is now approved to go to Mercy General in Muskegon and Metropolitan Hospital in Grand Rapids, will actually serve to reduce availability of this service in West Michigan in the future when Spectrum Health is not able to replace our HM3 and, therefore, will either go away or have far reduced service. I think this is an unintended consequence of the existing standards because I'm sure that the standards were not developed to reduce availability of a service.

You know, I'm obviously not reading my comments, but we think that it's important that successful services like the one that has existed in West Michigan these many years should be protected under Certificate of Need so that, in fact, service or availability of service is not diminished, and that there should be some sort of geographic allocation, if you will, or geographic planning for lithotripsy services.

Kind of the flip side of this, and this touches a little bit on what my friend Cheryl Miller just stated, is that the patients who do use mobile lithotripsy, even if there's not a backlog, because of the far-flung routes that those current routes have -- those current units have, they only come to, again, a particular site once or twice a month. So that even without a backlog -- and I can imagine with a backlog, it's much, much worse -- patients may need to be -- in the extreme may need to be hospitalized or at the very least may need to be stented, which therefore is then two procedures rather than one procedure and is actually more costly than just doing the first procedure the first time.

I think that it may be valuable for the standards to specify that mobile host sites need to have a minimum amount of service, you know, so many times per month, or conversely, that there should be a limit on the number of host sites that a particular mobile service has so that it's not so stretched that the service is sporadic or, you know, perhaps once a month.

In West Michigan we have seen a steady patient base. We have not seen an increase. It's been served well. And the standards as they're currently construed threaten to diminish, significantly diminish, the service that's available in West Michigan.

Those are my comments on behalf of Spectrum Health. Lody Zwarensteyn from the Alliance for Health called me yesterday and deputized me, so I forgot my badge, but I have been deputized. Basically I think Lody's comments are pretty much the same. He will be focusing on the availability of service to West Michigan. We have heard from representatives of the mobile service that serves the two sites in our area that their mobile service is over subscribed, that they have trouble providing sufficient volume or sufficient service to the existing host sites, and yet they have chosen to expand into an area that really didn't need additional service. So, you know, I think that some sort of limitation on that kind of expansion, some sort of concentration of that sort of service is important.

I can't imagine anything more -- "painful," I guess is the word, than being a patient with a very painful kidney stone and being told that the lithotriptor doesn't come back for two or three weeks and, therefore, either one of three things: Either grin and bear it; be hospitalized with extreme pain medication; or have a procedure now before the final procedure later. I don't think that's good patient care. I don't think it's good patient care for the existing sites for the mobile lithotriptors, and it's not the kind of care that we want in West Michigan as opposed to the reliable, always available open-staff model that is currently there. Thank you.

MS. ROGERS: Thank you. Ann Mitchell, United Medical Systems.

MS. MITCHELL: Good morning. I'm Ann Mitchell from United Medical Systems. Thank you for allowing me to speak today. First I'd like to respond to Bob's comment about the mobile provider going into West Michigan in order to eliminate service to West Michigan. That's appropriate. We didn't exactly choose to go after hospitals in West Michigan as a manager of

mobile service. The hospitals in West Michigan came to us and asked us if we could possibly provide service to them out there, so that we did what we could in order to give them what they needed.

But in any case, I represent United Medical Systems. We are a hired management and service provider to a group of hospitals who own the CON under contract for services for lithotripsy. A couple of years ago there was a bit of a crisis in the Southeast Michigan area where two aging lithotriptors were not able to be replaced without combining the two at Henry Ford and Harper in order to fulfill standards for replacement of lithotripsy equipment. So we took a very careful look at the situation to see what we could possibly do in order to remedy that in order to bring service to the greater community as well as fulfill the need for service in Detroit.

After looking very carefully at the all of the things that needed to be considered, including trying very hard to bring a broader community-based lithotripsy service into Michigan rather than a fixed-based service like it is in most other states -- you know, we wanted to serve as many people as was appropriate, so we looked at what the CON Standards allowed for and how the MIDB data is used in order to provide appropriate service to each of these sites. And what we turned up with was a whole host of hospitals who would satisfy the need for 1,000 cases, including actual cases done in one hospital and projected cases done in a number of others.

We knew that the MIDB data was not exactly the appropriate measure of, you know, what could be considered for 1,000 cases, and we were worried about that, but we had to do what we had to do. So we used that data. We concocted a situation in which 1,000 cases would exist in order to, you know, fulfill the standard for conversion of fixed-site service into mobile service, and we ran with it.

We found, of course, that we probably need a multiplier in the MIDB data instead of, you know, a fraction. And therefore, you know, we had reduced two lithotriptors, who could have probably been used more appropriately in mobile settings but that had been fixed, and achieved what was once 600 patients per year in two fixed sites and ran that up within one year's time to 1,000 -- or 2,000 cases, which is entirely appropriate for two machines.

So in any case, the method that we had to -- that we were made to use in order to achieve this goal was, you know, the -- pretty much how it was accomplished. There was no malice intended in going out after, you know, other people's CONs. And I don't think that, in looking at the data, we have affected any existing numbers that other providers provide service for. We've got 2,000 cases. We're still doing the same number of cases at Henry Ford and Harper that was being done before, even on a mobile service. We've got the data to provide you, the Department, with all that data, and yet I don't see that we could have done it any other way.

It's a very good service. Mobile service is pretty much the standard of care with lithotripsy because it's very cost effective. We would like not to have to operate on Saturdays because most hospitals don't want to have to provide additional staffing due to shortages as well as pay overtime. We have found that in a very concise data collection that the average number

of cases we are performing as opposed to predicted is about 261 percent higher rate than what was predicted by the MIDB data for the service.

We're proposing language that would remedy the situation because operationally it is difficult, you know, to provide a mobile service in an environment where we were required, you know, to use MIDB -- I mean, had we -- we wouldn't have been able to do -- we wouldn't have been able to achieve a mobile service whatsoever without using the MIDB data that we were allowed to use, so -- and people wanted the service, that was the thing. If they had wanted to donate their data without wanting service, it would be an entirely different story. But people have been very receptive to the service, and we do have physician testimony.

I think cooperative endeavors like this allow for very successful community-based healthcare. Everyone, rather just one or another, have a chance to provide this kind of service to their patients in their own communities with their own doctors, with the convenience, of course, of familiarity at the institutions that they choose.

We don't also -- we're here, and we've been coming since last September because we don't want patients to have to wait a long time as well. We're doing fine though. There have been no problems, you know, in regard to that, but, I mean, the potential is there, and we want to have a chance to avert the problems that could potentially exist. And I think it's very fair that, you know, each hospital system or each hospital that wants this kind of service and it can be provided should have the opportunity to get it. Don Pietruk is going to be supplying you with a language proposal change. Thank you very much.

MS. ROGERS: Thank you. Don Pietruk representing Henry Ford and Harper Hospitals.

MR. PIETRUK: Hi, my name is Don Pietruk. I'm here today representing Henry Ford-Harper Hospital Mobile Lithotripsy, Incorporated. Following up, United Medical Systems is the manager, the service manager, of that route. The CON is actually own by Henry Ford and Harper. Just to build upon what Ann had briefly had kind of expounded upon, in the packet that we submitted to the Department and to the Commission today you'll see that the utilization numbers in our first full year of operation of this route, in 2002, it was 1700 procedures. And if we take the period of July of 2002 to June of 2003, we're up to 1997 procedures on this route. So the route is definitely overly stressed. And we also gave some comparisons to out-routes that UMS operates which they consider to be fairly normal routes of operation around the country. And we're doing more than twice the volume, sometimes four, five times the volume of many of those routes.

So this is a highly efficient operation. We service a lot of patients and a lot of hospitals. Why we service so many hospitals is really a vagary of the CON system. We were forced to put together this coalition of hospitals to get enough MIDB data to qualify for the unit, basically when we -- coupling the utilization we had on the Henry Ford and Harper's machines, plus getting MIDB data, which was more heavily discounted at the time, so that we were forced to put this coalition of hospitals together in order to be qualified for the unit. And now that there are clients, they all have -- you know, they all have existing service, but they need actually more service.

Basically what we're proposing is two changes to the CON Standard, which we feel would accomplish our needs. First of all, we feel we need to add a definition for expanding an existing mobile UESWL service and a section in the standards that allows for expansion of existing services. Currently the CON Standard does not have a section for expansion of service, and that needs to be added in order for Henry Ford and Harper to get an additional unit, which we feel is -- you know, efficient utilization has shown it's necessary. And there are also letters in the packet we supplied from physicians, which document their need for more time than the route can deliver to them at the current -- in the current operating condition.

So we would propose adding a definition of expansion which would mean -- you know, expansion of a mobile service would be mean increasing the number of UESWL services/units operated by the same central service coordinator on an existing mobile route and a section -- an undefined section on expansion which says that as long as -- in order to expand an existing service, the operator of the route has to do at least 1800 procedures annually on the existing machine in order to qualify for an additional machine. That's the extent of what we're asking the Commission for. And I guess when we address the Commission we'll be happy to take any questions or comments that they have then. Thank you.

MS. ROGERS: Thank you. Barbara Jackson, Economic Alliance of Michigan.

MS. JACKSON: Good morning. My name is Barbara Jackson. I'm regulatory director for Economic Alliance of Michigan. We just wanted to sort of put our three cents in. And since it's me, it's three cents. If it was Larry, it would have been about 15.

At this time EAM has no official position on lithotripsy service standards; however, we are very interested in having the adequate number and distribution of lithotripsy units. Until recently we thought this area was addressed, as we believed this was not a growing diagnostic modality and the current supply was or is adequately distributed. In fact, previously there was a three-unit cap, and EAM supported increasing that number to five. EAM also supported exceptions based on the concerns of under-served areas and the ability to provide an even playing field for hospitals that wanted to operate their own systems.

If utilization warrants, we are interested in allowing new entrants into the market, but not by only allowing current providers to do so. If there is a need for additional lithotripsy services, we would like to see the data which demonstrate the increased demand and utilization distribution as well as addressing the provision to deliver services in the previously under served area. It's helpful for us to be here to listen and learn and ask, so we are interested in receiving feedback from others and reviewing current utilization data. Thank you.

MS. ROGERS: Thank you. That's the last of the cards I have. Does anybody else wish to provide testimony today regarding lithotripsy? Linda Prister, Michigan Mobile Lithotripsy.

MS. PRISTER: Good morning. Thank you. Usually my colleague Dale Downs usually comes here and speaks but -- out of town. I wanted to take an opportunity to present Michigan Mobile Lithotripsy. As many of you know, Michigan Mobile Lithotripsy is probably the original mobile unit in Michigan. We've been in existence for probably about 14 years.

The volume that we see on our route for a mobile unit has increased every year. We are in excess of 2,000 cases in our one mobile unit. We provide the service.

As many of the ladies and gentlemen have stated in this meeting this morning, had identified, that we need to look at, you know, the potential for expansion, especially when, you know, the volume warrants it. MML has been in existence as a joint venture between Oakwood Healthcare System, St. John Healthcare System and Sparrow Hospital. We've been extremely successful. We have mentioned oftentimes this morning that what the issue is, is the convenience level. And it's not a convenience level. What it is, it's an inherent quality issue for patients.

Patients need to be able to receive the service. I don't have to, you know, reiterate many of the, you know, issues that were stated, but as a nurse, I can tell you that the stenting and the additional procedures is not just an additional procedure for a patient. It increases infection. It increases, you know, potential for additional surgical procedures down the road. If the service is available, we should be able to provide it.

Many of our providers are in excess. Our hospital here, Sparrow, is identifying that the frequency of every three weeks is not enough. All right? The patient demand is there. What we're asking for is very much like our UMS colleagues, is that we're asking for an expansion, and we're asking for us to be able to look at the volume that is warranted on these individual units. And that is the position of MML, and we ask you to be able to please review it for the future. Thank you.

MS. ROGERS: Thank you. Any further testimony? Raj Wiener representing United Medical Systems.

MS. WIENER: Good morning. My name is Raj Wiener. I just want to make one quick comment. Lithotripsy is one of the few services in Certificate of Need that is still under comparative review. For MRI, MRT, CT, everything else, we have moved to facility-specific standards. And there was a good reason why over the years the State has moved in this direction. It's because, when you have comparative review, most often the cost of litigation exceeds the cost of the equipment or the services for several years as they're being offered.

And there is good documentation on the utilization on the amount of service that is needed in the rest of the state. The proposals that you heard earlier suggested a facility type of expansion for these services. I wanted to comment on the approach that the Economic Alliance has suggested, which is to treat these as initiations in -- by way of looking at the cap. I believe that that methodology will only result in litigation and no increased services in the state and want to urge the Department and the Commission to revise the CON Standards for lithotripsy to be facility specific. Thank you.

MS. ROGERS: Thank you. Any further testimony? Okay. Hearing none, this hearing is adjourned at 10:32.

(Proceedings concluded at approximately 10:32 a.m.)